

JUN 13 2001

K011134

SECTION 20

510(K) SUMMARY

Hudson RCI Over the Counter Oxygen Supply Tubing

1.0 Date

April 9, 2001

2.0 Submitter

Hudson Respiratory Care, Inc.
27711 Diaz Road
Temecula, California 92590

3.0 Contact Person

Jeannie L. Denning ASQ CQA

4.0 Telephone

(909) 676-5611, ext. 1232

5.0 Proprietary Device Name

Hudson RCI Over the Counter Oxygen Supply Tubing

6.0 Classification Name

Pressure Tubing and Accessories

7.0 Common Name

Oxygen Supply Tubing

8.0 Predicate Device

Hudson RCI Oxygen Supply Tubing

000051



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2001

Ms. Jeannie Denning
Hudson Respiratory Care, Inc.
27711 Diaz Road
P.O. Box 9020
Temecula, CA 92589-9020

Re: K011134
Oxygen Supply Tubing, Model 1115
Regulation Number: 868.5860
Regulatory Class: I (one) exempt
Product Code: 73 BYX
Dated: April 9, 2001
Received: April 13, 2001

Dear Ms. Denning:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

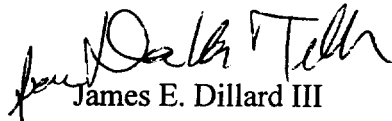
Page 2 - Ms. Jeannie Denning

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known):

CONFIDENTIAL

Device Name: Hudson RCI Over the Counter Oxygen Supply Tubing

Indications for Use:

Hudson RCI Over the Counter Oxygen Supply tubing is used as a conduit connecting an oxygen source to an oxygen delivery device (such as a mask or nasal cannulae) in order to provide low flow oxygen to patients who require supplemental oxygen therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K011134

Over the Counter Use Only

000005